



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

HFI-35 1/23/01
ms074n
Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-25

January 18, 2001

Publio J. Labrador, Jr., President
Labrador & Son Food Products
1434-1438 NW 82nd Avenue
Miami, Florida 33126

Dear Mr. Labrador:

We inspected your seafood storage warehouse on November 20-21, 2000 and found that you continue to have a serious deviation from the seafood (HACCP) regulations (21 CFR Part 123) that was previously seen during our inspections of July 26-27, 1999 and February 2-8, 2000. This deviation causes your dried, salted, or pickled herring, mackerel, and other fish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and these regulations through links in FDA's home page at www.fda.gov.

You replied to the November 2000 inspection by an undated letter in which you provided corrective measures to the violations uncovered during the inspection. We reviewed your response and found that most of the corrective actions given appear satisfactory. However, we still have concern with your proposed product specifications for the imported seafood products, in that:

You failed to maintain adequate product specifications that list all appropriate safety hazards and/or limits for seafood products imported by your firm [21 CFR 123.12(a) (2) (i)]. This deviation was previously brought to your attention in our letter dated August 19, 1999. The product specifications must be relevant to the product safety for fish and fishery products that you import.

In addition, you stated during the inspection that none of the seafood products handled by your firm are smoked. However, you submitted a HACCP plan example for smoked fish that failed to include C. Botulinum toxin formation as a significant hazard. Also, your HACCP plans provided for review fail to include thermometer calibration as part of the verification procedures.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act and the Seafood HACCP regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. We may take further action if you do not promptly correct this violation. For instance, we may seize your products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation such as a copy of your written product specifications for imported seafood products and your revised HACCP plans or other useful information that would assist us in evaluating your corrective action. If you cannot complete correction before you respond, we expect that you will explain the reason for your delay and state when you will correct this deviation.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long, sweeping horizontal line extending to the right.

Emma R. Singleton
Director, Florida District